REMARKS

Claims 79-108 are in the application.

The claims have been amended to more particularly point out and distinctly claims applicant's invention, and to limit the claims to the elected subject matter. Claims to non-elected subject matter have been cancelled, and claims drawn to elected subject matter (claims 41-44 and 53-78) have been rewritten for clarity as new claims 79-108. The new claims are supported in the application as filed and include no new matter.

The Examiner has required restriction of one of the following inventions pursuant to 35 U.S.C. § 121 and 372. The Examiner states that the following inventions or groups of inventions are not linked so as to form a single general inventive concept under PCT Rule 13.1, and has required the applicant to elect a single invention to which the claims must be restricted.

Group I, claims 41-49, 51, 54, and 56-78, drawn to a sustained release viscous composition, classified in class 424, subclass 455.

Group II, claims 41-45, 50-51, 54 and 56-78, drawn to a sustained release viscous composition, classified in class 424, subclass 455.

Group III, claims 41-44, 52, 54, and 56-78, drawn to a sustained release viscous composition, classified in class 424, subclass 455.

Group IV, claims 41-44 and 53-78, drawn to a sustained release viscous composition, classified in class 424, subclass 455.

Applicant elects Group IV, corresponding to prior claims 41-44 and 53-78 and new claims 79-108, with traverse.

The Examiner has further required an election of species of the generic invention.

The Examiner further states that the inventions listed in Groups I, II, III and IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features.

The Examiner cites U.S. Patent 6,503,955 ("Dobrozsi") as teaching pourable liquid vehicles to deliver compositions. The Examiner states that one embodiment contains oxymetazolin HCl (active ingredient), monobasic and dibasic phosphate (release modulator), Pluronic F127 (synthetic lipid colloid), and ethanol (solvent), citing col. 12, Example VIII. The Examiner concludes that as such claim 41 (Group II) does

not possess a special technical feature, and unity between Groups I, II, III and IV is broken.

The Examiner states that the application contains claims directed to more than one species of the generic invention, and has required the make the following species elections:

(a) One type of polymer from claim 45 (natural or synthetic);

(b) One natural polymer from claim 46.

(c) One synthetic polymer from claim 50.

(d) On form of active ingredient from claims 58-61.

(e) One release modulator ingredient from claims 63.

Applicant makes the following elections, with traverse:

With respect to (a), applicant elects: synthetic.

With respect to (b), applicant elects: cellulose.

With respect to (c), applicant elects: copolymers of acrylic acid.

With respect to (d), applicant elects: solid.

With respect to (e), applicant elects: hydrophilic additive class.

The Examiner's restriction requirement based on the alleged lack of unity of invention is traversed for the following reasons:

Based on the Group IV election, the application is in accordance with the Rule 13.1 of the Patent Cooperation Treaty, due to the fact that the Group IV claims forms a single general inventive concept.

This unity is based on the utilization of invert latexes, special new liquid or pasty ingredients in pharmacy and cosmetic, which have the properties to instantaneously form matrices, more or less compact, in contact with water or gastric juice, from which active substances can be released slowly.

The unity is given by the fact that all claims are tied to claim 79 or each other. Indeed:

- Claims 80 and 83 relate to the nature of the matrix: invert latex of derivatives of acrylic acid or of acrylamide polymers.
- Claims 81 and 82 relate to the mechanism of matrix formation.
- Claims 84 and 85 relate to the invert latex concentration and the corresponding viscosity, needed to obtain matrixes.

- Claim 86 relates to what kind of active substances can be incorporated in these invert latexes. If there are no actives, there would be no purpose to use invert latexes for sustained release.
- Claims 88 to 91 relate to how actives substances can be incorporated in the invert latex to obtain the best release through this new sustained release system.
- Claim 92 relates to modulating the sustained of the active substances through this new system.
- Claims 93 to 95 relate to amplifying the sustained release effect from the invert latex: using hydrophilic substances at the solid step which are going to swell and to increase the hardness of the matrix.
- Claims 97 and 98 relate to how the invert latex matrix can be resist to the intestinal contractions. Without plasticizer the matrix is going to be broken under the intestinal contractions.
- Claims 99 to 104 relate to helping the dissolution of some active substances by using:

• Surfactants, like for fenofibrate, a well known example of the any person skill in the Art. Fenofibrate is an insoluble active. Its dissolution is increased by micronizing it with sodium laurylsulfate, a surfactant.

• Polyols, to facilitate the water penetration in the matrix without having an effect on the matrix structure.

• Buffer solutions, to create an acid or alkaline micro environment inside the mixture of invert latex, to:

  ° facilitate the dissolution of some active substances like quinine. Quinine is insoluble in alkaline medium, by creating an acid medium inside the matrix, the quinine is going to be dissolved inside the matrix and release through the matrix under a acid liquid step.

  ° maintain the active substance under a solid step.

  ° increase the viscosity of the invert latex gel instantaneously formed in contact with gastro intestinal juice, just after the opening of the capsule.

- Claims 105 to 108 relate to some parameters of the sustained release from these matrices and how to package the invert latex : soft and hard capsules.

It should be noted that U.S. Patent 6,503,955 describes a “pourable liquids” for moistening surfaces and aqueous environments.

These “pourable liquids" contain water from 1% to 50%.

However, in the presently claimed invention, no water is added to the invert latex due to the fact that the mixtures developed with this new ingredient have to be filled in soft and hard capsules. One of ordinary skill in the art would understand that the "pourable liquids" of the '955 Patent could not be used for filling capsules since the water would tend to dissolve the capsule walls, rendering the capsules unusable for their intended purpose.

The specific "liquid matrix ingredients" disclosed by the '955 Patent are polyoxalkylene block copolymer, ethylene oxide and propylene oxide copolymer. These polymers are not presently claimed.

The purpose of the presently claimed invention is not to moisten surfaces but to release slowly active substances in the gastro intestinal tract. Nothing in U.S. Patent 6,503,955 speaks about or suggests the sustained the release of active ingredients. Moreover nothing in the '955 Patent discloses or suggests that monobasic and dibasic phosphate act like a release modulator. Rather, they are simply buffer ingredients to keep the pH of the “pourable liquid” around pH 7 for a nasal application. Any person skilled in the art knows that the pH of nasal solutions must be around 7.

Therefore the U.S. Patent 6,503,955 does not disclose or suggest the special technical features of the presently claimed invention and does not destroy the unity of the invention.

Reconsideration and withdrawal of the restriction requirement is respectfully requested for these reasons.

It is respectfully noted that given the election of Group IV and concomitant amendment of the claims, the Examiner's species restriction requirements of one type of polymer from claim 45 (a), one natural polymer from claim 46 (b) and one synthetic polymer from claim 50 (c) become meaningless, and reconsideration and withdrawal of these species restriction requirements are respectfully requested for this reason. Nevertheless, should the Examiner maintain the species restriction requirements, applicant's species elections are provided above.

Applicant also respectfully requests withdrawal of the Examiner requirement to elect a species based on the physical form of active ingredient, since many if not all can assume either a liquid form or solid form. Examples of such species include:

- alverine : base : liquid form

HCl salt : sirup form

Citrate : solid form

- benfluorex : base : liquid form

HCl salt : solid form

- benoxinate : base : liquid form

HCl salt : solid form

- cadaverine: base : liquid form

HCl salt : solid form

A similar situation obtains regarding:

- molecules optically active (d form, l form or dl form)
- molecules having a radical in para, ortho, or meta
- molecules having an asymmetric carbon giving a cis from or a trans form.

Therefore, electing either a solid or a liquid is essentially meaningless.

It should be noted that some molecules are more active therapeutically speaking in one form than in the other form. Thus, if we choose to elect a solid form instead of liquid form and if some active substances are more active therapeutically speaking as liquids, making a sustained release form of this active as a solid form would reduce the activity of the final product.

Similarly, the required election between release modulator ingredients brings up the same considerations as the required election as to the active ingredients:

- a syrup like flavors, preservatives, coloring agent, buffer ingredients, sweeteners,
- a tablet like, binders, lubricants, coating ingredients, coloring agents, etc.…

In the '955 Patent the applicant adds other ingredients like menthol, eucalyptus, sodium saccharinate, monoammonium glycerizzinate, flavors and colors (example III), triclosan monophosphate (example VII), dibasic sodium phosphate, monobasic potassium phosphate, benzalkonium chloride, chlorhexidine gluconate, disodium EDTA (example VIII), etc. Thus, no choice was appropriate as to the other ingredients added to his formulations. These ingredients permit to obtain an optimum in the activity of his final product, like preservatives or buffer ingredients.

Reconsideration and withdrawal of the restriction requirement and species election requirements are respectfully requested for these reasons.